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EXAMINER	
BURKHART, MICHAEL D	

ART UNIT	PAPER NUMBER
1633	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/788,847	NAKAMURA ET AL.	
	Examiner	Art Unit	
	Michael D. Burkhart	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-61* is/are pending in the application.

4a) Of the above claim(s) *1-14 and 16-61* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *2/27/2004 and 04 December 2006* is/are: a)☒ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/18/04; 4/29/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election of Group VII, claim 15, in the reply filed on 2/27/2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-14 and 16-61 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 2/27/2007.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Canada on 8/23/2002. It is noted, however, that applicant has not filed a certified copy of the 2,399,569 application as required by 35 U.S.C. 119(b).

Claim Objections

Claim 15 is objected to for depending from non-elected claims (claims 1 and 5).

Claim 15 is objected to because of the following informalities: "cell" in line 5 should be "cells." Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 15 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods using the ZNFN3A1 protein set forth in SEQ ID NO:2 and encoded by a portion of SEQ ID NO: 1, does not reasonably provide enablement for other ZNFN3A1 proteins comprising two or more substitutions, partial peptides of SEQ ID NO: 2, or ZNFN3A1 proteins encoded by DNA that hybridizes to SEQ ID NO: 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Claim 15 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

While the written description and enablement requirements are separate and generally separable requirements, the instant application fails to meet either requirement for essentially the same reasons, as set forth below.

Applicants claim methods to screen for compounds that inhibit the ZNFN3A1 protein, disclosed as a protein involved in the transformation of tumor cells, or the ZNFN3A1 variants set forth above. Applicants disclose the amino acid and DNA sequences of a single ZNFN3A1 protein, isolated from human tumor cells, with transformation activity. The claim reads on methods using a broad genus of ZNFN3A1 proteins (e.g. not limited to human ZNFN3A1) and variants, such as any sequence that hybridizes to the portion of SEQ ID NO:1 under stringent

conditions (which are not definitively defined in the specification, and thus include low stringency conditions), or any amino acid sequence with one or more substitutions relative to SEQ ID NO: 2.

The written description requirement for a genus may be satisfied by sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between structure and function, or by a combination of such identifying characteristics, sufficient to show that applicant was in possession of the claimed invention. The court and the Board have repeatedly held (Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.,18 USPQ2d 1016 (CA FC, 1991); Fiers v. Revel, 25 USPQ2d 1601 (CA FC 1993); Fiddes v. Baird, 30 USPQ2d 1481 (BPAI 1993) and Regents of the Univ. Calif. v. Eli Lilly & Co., 43 USPQ2d 1398 (CA FC, 1997)) that an adequate written description of a nucleic acid requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it, irrespective of the complexity or simplicity of the method; what is required is a description of the nucleic acid itself. It is not sufficient to define DNA solely by its principal biological property, because disclosure of no more than that, as in the instant case, is simply a wish to know the identity of any DNA with that biological property. Naming a type of material generically known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. When one is unable to envision the detailed constitution of a complex chemical compound having a particular function, such as a nucleic acid or protein, so as to distinguish it from other materials, as well as a method for obtaining it, conception has not been achieved until reduction to practice has

occurred, i.e., until after the nucleic acid has been isolated. Thus, claiming all DNA's that achieve a result without defining what means will do so is not in compliance with the description requirement. Rather, it is an attempt to preempt the future before it has arrived. Also, where a claim purports to cover all nucleic acids that encode a specific protein and the specification discloses but a single DNA known to do so, the situation is analogous to a single means claim and does not meet the enablement requirement under para. 1 of §112. The court has also held that a claimed nucleic acid could meet the written description and enablement requirements if the nucleic acid were defined by a disclosed process found, after-the-fact, to produce the nucleic acid, and claimed as a product-by-process. However, in the instant case, the nucleic acids are not claimed as a product-by-process, nor does the specification disclose any process known to yield a claimed nucleic acid.

In terms of the structural requirements of the nucleic acid molecules, claim 15 recites an arbitrary structural relationship between the claimed nucleic acid sequence(s) and the single disclosed species of nucleotide sequence and amino acid sequence, respectively, based upon hybridization of nucleic acid. Hybridization of two nucleic acids, even under high stringency conditions, requires only that the two nucleic acids share between 25 and 50 nucleotides in common. See Kennell, Progr. Nucleic Acid Res. Mol. Biol. 11: 259-301, 1971 at the paragraph bridging pages 260-261. Such a sequence encodes only 8-16 amino acids. Consequently the claims embrace polypeptides that could share as few as 8-16 contiguous amino acids in common out of the 428 amino acids of SEQ ID NO: 2. Conversely, a nucleotide sequence that differs in every wobble base from SEQ ID NO: 1, for example, would encode SEQ ID NO: 2, but would not detectably hybridize to SEQ ID NO: 1 under any conditions. Thus, the recited structural

relationship is arbitrary since neither the specification nor the prior art discloses any definitive relationship between protein function and % identity or homology at the nucleotide level; and the specification does not describe a single species of nucleic acid that encodes a functional protein that is not either 100% identical to SEQ ID NO: 1 or that encodes a polypeptide that is not 100% identical to SEQ ID NO: 2.

While one of skill in the art can readily envision numerable species of nucleic acid sequences that are at least a given % identity to a reference nucleotide sequence and that encode a polypeptide at least a given % identity to a recited reference amino acid sequence, one cannot envision which of these also encode a polypeptide with a specified activity. The fact remains that the actual nucleic acid sequences which encode a protein with a particular activity or the actual amino acid sequences of such a protein cannot be envisioned any better when the possible choices are narrowed from all possible sequences to all possible sequences with an arbitrary structural relationship with a known functional sequence. For example, if one skilled in the art were to make a synthetic nucleotide sequence that encoded a polypeptide with 90% identity to the reference amino acid sequence, he would be no more able to say whether it encoded a functional ZNFN3A1 than if the nucleotide sequence encoded a polypeptide that was only 10% identical to the reference polypeptide sequence. Nor would he be able to say whether the sequence existed in nature.

In the instant case, applicants only disclose the human ZNFN3A1 sequences (i.e. the amino acid sequence of SEQ ID NO: 2, and the associated nucleic acid sequence of SEQ ID NO: 1), with no disclosure of the function or activity of the ZNFN3A1 protein. Also disclosed is a mouse amino acid sequence (AK010447, Fig. 2B) that is 94% homologous to SEQ ID NO: 2 at

the amino acid level, however, the activity of the murine sequence is unknown. Applicants are claiming other forms of ZNFN3A1, and ZNFN3A1 variants, by function only, without a correlation between structure and function. Applicants provide no disclosure of what structural feature(s) of the instantly disclosed ZNFN3A1 are responsible for the observed association with tumor cell transformation/cell proliferation. There is only a broad disclosure that homology modeling tools indicated the ZNFN3A1 protein contains a zinc-finger domain, that a yeast two-hybrid screen demonstrated ZNFN3A1 binds to an RNA helicase, and that a consensus DNA sequence is recognized by ZNFN3A1. There is no disclosure of mutants, variants, or partial peptides of ZNFN3A1 that retain the transformation/cell proliferation activity. Thus, the diversity of the ZNFN3A1 sequences to be used in the claimed method, along with the lack of disclosure regarding other functional ZNFN3A1 sequence variants, would require the skilled artisan to conclude that the single ZNFN3A1 sequence presented by the applicants is not sufficient to describe the claimed genus.

The specification does not provide any information on what amino acid residues are necessary and sufficient for the disclosed ZNFN3A1 properties, such as transformation/cell proliferation. The specification also provides no teachings on what amino acid sequence modifications, e.g. insertions, deletions and substitutions, would be permissible in a variant polypeptide that would improve or at least would not interfere with the biological activity or structural features necessary for the biological activity and stability of the protein. Since there were no other examples of a functional ZNFN3A1 protein known that have structural homology with SEQ ID NO: 2, it is not possible to even guess at the amino acid residues which are critical to its structure or function based on sequence conservation. The comparison of SEQ ID NO: 2 to

the murine AK010447 sequence is no help because of the function of AK010447 is not disclosed or known. Furthermore, it is known in the art that even conservative amino acid substitutions can adversely affect proper folding and biological activity if amino acids that are critical for such functions are substituted, and the relationship between the sequence of a polypeptide and its tertiary structure is neither well understood nor predictable (see Ngo, in The Protein Folding Problem and Tertiary Structure Prediction, Merz et al. (eds.), Birkhauser Boston: Boston, MA, pp. 433 and 492-495, 1994). Rudinger (in Peptide Hormones, Parsons (ed.), University Park Press: Baltimore, MD, pp. 1-7, 1976) discloses that even for peptide hormones, which are much smaller than the instant ZNFN3A1 protein, one cannot predict variant amino acid sequences for a biologically active polypeptide. Rather one must engage in "case to case painstaking experimental study" to determine active variants (see page 7). Consequently, excessive trial and error experimentation would have been required to identify the necessary ZNFN3A1 protein derivatives with an activity of SEQ ID NO: 2 since the amino acid sequence of such polypeptides could not be predicted - even were the activity known.

As set forth in *In re Fisher,* 166 USPQ 18 (CCPA 1970), compliance with 35 USC 112, first paragraph requires:

> that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved.

In *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991), the court ruled that a claim to a large genus of possible genetic sequences encoding a protein

with a particular function that needs to be determined subsequent to the construction of the genetic sequences may not find sufficient support under 35 USC 112, 1st para., if only a few of the sequences that meet the functional limitations of the claim are disclosed and if undue experimentation would be required of one skilled in the art for determining other genetic sequences embraced by the claim. This is the case here, where the specification discloses only one putative functional amino acid sequence, SEQ ID NO: 2, for a polypeptide having the necessary activity, and provides no guidance on determining which polypeptide variants of SEQ ID NO: 2 that would have an activity of SEQ ID NO: 2.

To put the situation in perspective, the number of possible amino acid sequences of 428 amino acids in length (SEQ ID NO: 2 is 428) is 20^{428} (approx. 10^{556}). The number of possible nucleotide or amino acid sequences that are of a given % identity relative to a reference sequence, where all differences between the possible sequences and the reference sequence are substitutions, can be calculated by the following expansion formula:

$$N = XL + X^2L(L-1)/2! + X^3L(L-1)(L-2)/3! + \ldots + X^{n-1}L(L-1)(L-2)\ldots(L-(n-2))/(n-1)! + X^nL(L-1)(L-2)\ldots(L-(n-1))/n!$$

where N is the number of possible sequences, X is the number of different residues that can be substituted for a residue in the reference sequence, L is the length of the reference sequence, n is the maximum number of residues that can be substituted relative to the reference sequence at a given % identity. For a nucleotide sequence, X is 3 (alternate nucleotides); for an amino acid sequence, X is 19 (alternate amino acids). The n^{th} term of the expansion can be rewritten as:

$$X^n \cdot {}^{L!}/_{n!\,(L-(n-1)!}$$

For a 428 amino acid sequence that is at least 98% identical to a reference sequence of 428 amino acids, e.g. SEQ ID NO: 2 with 8 substitutions, the number of possible sequences having 7 amino acid substitutions relative to the reference (the penultimate term of the formula) is approximately 1.1×10^{21}, whereas the number of possible sequences having 8 amino acid substitutions relative to the reference (the final term of the formula) is approximately 1.1×10^{24}. So the last term is approximately equal to N, i.e. the preceding terms contribute little to the total. Also, as the number of permitted substitutions increases (the claimed variants of ZNFN3A1 have no upper limit on the number of substitutions, see claim 1) the number of possible variant sequences increases geometrically.

Claim 15 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of screening for RNAi that inhibit the activity of the protein of SEQ ID NO: 2, does not reasonably provide enablement for methods of screening for any other compound. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the application coupled with information known in the art without undue experimentation (*United States v. Telectronics,* Inc. 8 USPQD2d 1217 (Fed. Cir. 1988)). Whether undue experimentation is required is a conclusion reached by weighing several

factors. These factors were outlined in *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Inter. 1986) and again in *In re Wands*, 8 USPQQ2d 1400 (Fed. Cir. 1988) and include the following:

Unpredictability of the art and state of the art. The art concerning methods of screening for compounds that inhibit the activity of SEQ ID NO: 2 (ZNFN3A1) by culturing ZNFN3A1-expressing cells with and without the compound, then comparing the proliferation of the cells, is unpredictable. This is because there is no nexus between any observed differences in proliferation due to the compound and ZNFN3A1. Chiosis et al (2002) and Fantin et al (2002) both teach methods of screening for molecules that inhibit proliferation of tumor/cancer cell lines, and identify molecules through the screenings that inhibit proliferation. None of the molecules identified in either reference exert their effects through ZNFN3A1 (Fantin et al describe inhibitors of mitochondrial function, and Chiosis et al describe inhibitors of Hsp90). However, if the compounds identified in Fantin et al or Chiosis et al were applied to the method of instant claim 15, they would, absent evidence to the contrary, inhibit cell proliferation and be identified, incorrectly, as inhibitors of ZNFN3A1. The same is true for any other broad-spectrum anti-proliferative compound, such as doxorubicin or anthracycline. This is because the claim requires no link between an inhibition of proliferation and ZNFN3A1 inhibition. Even if it did, the state of the art regarding linking an inhibition of proliferation to ZNFN3A1 inhibition is poorly developed. This is because the function of the protein is not disclosed, hence assays for its activity (other than proliferation, as discussed above) were not available at the time of filing. The development of such methods and assays, as well as the elucidation of the activity of ZNFN3A1, would have to be done empirically.

Number of working examples and amount of guidance. Other than using RNA interference to target the expression of ZNFN3A1, applicants have provided no other working examples of the claimed method. Applicants provide no direction or guidance for other embodiments of the claimed method, in particular how one of skill in the art could determine if any inhibition of cell proliferation could be linked to ZNFN3A1 inhibition. The specification requires the skilled artisan to practice trial and error experimentation to determine methods of linking ZNFN3A1 inhibition to proliferation inhibition as claimed.

Scope of the invention. The claims are broad in nature and read on using any compound with any variant or fragment of SEQ ID NO: 2.

Nature of the invention. The invention involves the unpredictable art of screening for compounds that inhibit the activity of ZNFN3A1 by culturing ZNFN3A1-expressing cells with and without the compound.

Level of skill in the art. While the level of skill in the art of screening ZNFN3A1-expressing cells with and without a compound is high, the level of skill in the art of determining if such a compound inhibits ZNFN3A1 is low. The unpredictability of the art, lack of guidance, broad scope of the claims and poorly developed state of the art would require that undue and excessive experimentation would have to be conducted by the skilled artisan in order to practice the claimed invention.

Given the above analysis of the factors which the courts have determined are critical in determining whether a claimed invention is enabled, it must be considered that undue and excessive experimentation would have to be conducted by the skilled artisan in order to practice the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 recites the limitation "the proliferation" in line 5. There is insufficient antecedent basis for this limitation in the claim.

Drawings

New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the Drawings submitted 12/4/2006 are not marked as "Replacement Sheets." See below. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

Replacement Drawing Sheets

Drawing changes must be made by presenting replacement sheets which incorporate the desired changes and which comply with 37 CFR 1.84. An explanation of the changes made must be presented either in the drawing amendments section, or remarks, section of the amendment paper. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). A replacement sheet must include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of the amended drawing(s) must not be labeled as "amended." If the changes to the drawing figure(s) are not

accepted by the examiner, applicant will be notified of any required corrective action in the next Office action. No further drawing submission will be required, unless applicant is notified.

Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and within the top margin.

Annotated Drawing Sheets

A marked-up copy of any amended drawing figure, including annotations indicating the changes made, may be submitted or required by the examiner. The annotated drawing sheet(s) must be clearly labeled as "Annotated Sheet" and must be presented in the amendment or remarks section that explains the change(s) to the drawings.

Timing of Corrections

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.85(a). Failure to take corrective action within the set period will result in ABANDONMENT of the application.

If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings MUST be filed within the THREE MONTH shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael D. Burkhart whose telephone number is (571) 272-2915. The examiner can normally be reached on M-F 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael D. Burkhart
Examiner
Art Unit 1633